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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,518	11/16/2001	William Fenical	6627-PA1022	7755
7590 08/20/2004				
LISA A. HAILE, ESQ. GARY CARY WARE & FREIDENRICH LLP 4365 EXECUTIVE DRIVE SUITE 1100 SAN DIEGO, CA 92121		EXAMINER MARX, IRENE		
		ART UNIT PAPER NUMBER		
		1651		
DATE MAILED: 08/20/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/991,518	Applicant(s) FENICAL ET AL.	
	Examiner Irene Marx	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 13-20, 23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) 23-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 13-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/26/04 has been entered.

Claims 1 and 13-20 are being considered on the merits.

Newly submitted claim 23 and 24 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claims 1 and 13-20 are drawn to a strain of *Salinospora* and method of using this strain to make pharmaceuticals, classified in class 435, subclass 252.1, for example.

Claims 23 and 24 are drawn to a chemical compound and pharmaceutical composition, classified in class 514, subclass 412, for example.

Each of groups I and II is directed to separate and distinct inventions, Group I is directed to strains of microorganisms belonging to a specific species, while group II is directed to chemical compounds and a pharmaceutical composition. The products of groups I and II would be expected to have distinct morphological, functional and physiological properties as evidenced by divergent classification, process of making and process of using. In addition the microorganisms may be used in a process for obtaining antibodies or as host cells in processes involving the use of recombinant DNA or for the production of single cell protein for nutritional supplementation.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 23 and 24 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1 and 13-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for “wherein the position numbers 207, 366, 467, and 468 correspond to the *E. coli* numbering system” and in claim 13 of “wherein the position number 1456 corresponds to the *E. coli* numbering system”. There is nothing on the instant record to establish that the positions 207, 366, 467, etc. are invariant and are the sole and conventional numbering system for sequences of 16S rRNA of Actinomycetes and that they, in fact, “correspond to the *E. coli* numbering system” as now claimed.

Insertion of the limitation “correspond to the *E. coli* numbering system” does not have support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of the concept of “correspond to the *E. coli* numbering system” This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate possession of a concept after the fact. Thus, the insertion of “correspond to the *E. coli* numbering system” is considered to be the insertion of new matter for the above reasons.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants provide references and a table as basis for arguments. However, the arguments do not pertain to the invention as claimed. Applicant indicates that in Table 1, the first *Salinospira* (MAR1) signature nucleotide occurs at nucleotide position 207 in the *E. coli* sequence. When aligned by the automated system in the RDP, the same nucleotide 207 shares the space 713 and cites Mincer, et al., Appl Environ Microbiol , 68(10) (2002) pp. 5005-5011, for further information. The claims as written merely pertain to “corresponds to the *E. coli* numbering system”. It is not set forth how it “corresponds”, such as indication of an alignment

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or how it is achieved. Moreover, there is no clear explanation regarding the correlation between “the *E. coli* numbering system” and the “RDP alignment” as set forth in Table 1. In addition, applicant has not provided evidence to justify the automatic extrapolation of information pertaining to “MAR1” to all strains of *Salinospora* or whether this strain freely available to the public. It is also noted that the touted information presented in Table 1 does not appear to be part of the as-filed specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 13-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 13 are vague and indefinite in the recitation of certain positions in the 16S rRNA without an indication of the context of these positions. Applicants now indicate that the position numbers “correspond to the *E. coli* numbering system”. The record is unclear regarding the universality of the “*E. coli* numbering system”. Moreover, the term “corresponds” is ambiguous and open to interpretation. How is “correspondence” to be assessed, considering that the respective sequences in *Salinospora* are not fully identified? The precise length of the intended sequences is unknown. That sequences are conserved does not necessarily mean that their length is invariant. Depending on the variation in length and where counting starts, position 300 in one sequence may not be at the same location in another sequence. The precise meaning of applicant’s intended positions cannot be readily determined. Applicant should provide a reference sequence, for example. At paragraph [0026] applicants indicate “(*E. coli* number system)”. However, it is unclear how this “numbering system” “corresponds”. Moreover, the claimed invention makes no reference to any numbering system or the presence of certain “signature nucleotides”, as now alleged.

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Thus the "correspondence" appears to be approximation at best. Thus the strains intended are not properly identified and the invention is not particularly pointed out and distinctly claimed.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants provide references and a table as basis for arguments. However, the arguments do not pertain to the invention as claimed. Applicant indicates that in Table 1, the first *Salinospora* (MAR1) signature nucleotide occurs at nucleotide position 207 in the *E. coli* sequence. When aligned by the automated system in the RDP, the same nucleotide 207 shares the space 713 and cites Mincer, et al., Appl Environ Microbiol , 68(10) (2002) pp. 5005-5011, for further information. The claims as written merely pertain to "corresponds to the *E. coli* numbering system". It is not set forth how it "corresponds", such as indication of an alignment or how it is achieved. Moreover, there is no clear explanation regarding the correlation between "the *E. coli* numbering system" and the "RDP alignment" as set forth in Table 1. In addition, applicant has not provided evidence to justify the automatic extrapolation of information pertaining to "MAR1" to all strains of *Salinospora* or whether this strain freely available to the public. It is also noted that the touted information presented in Table 1 does not appear to be part of the as-filed specification.

Rejections under 35 U.S.C § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ a specific strain of *Salinospora* to produce the product Salinosporamide A. It is not clear if the written description is sufficiently repeatable to avoid the

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need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.

It is not apparent whether a deposit was made in this application as filed that meets all of the criteria set forth in 37 CFR 1.801-1.809. A strain of *Salinospora* appears to have been deposited at the ATCC under accession number ATCC PTA-250 for comparison purposes (Specification, bridging paragraph between pages 3 and 4). However, there is no indication regarding the availability of this deposit to the public and whether this strain produces Salinosporamide A. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner.

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.
2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.
3. States that the deposited material has been accorded a specific (recited) accession number.
4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.
5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.
6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.
7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true,

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and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

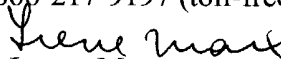
Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Irene Marx
Primary Examiner
Art Unit 1651